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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,399	11/10/2005	Stephen Peroutka	SYNER-003	6277

23599 7590 07/27/2006

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/556,399	PEROUTKA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. US 4,690,949, in view of Ogorka et al. US 2001/0033866 A1.

Yoshida teaches a therapeutic composition comprising L-threo-3,4-dihydroxypheylserine (L-threo-DOPS) (abstract; and column 6, lines 23-42). The composition further comprises excipients suitable for oral administration (column 6, lines 43-57; and claims 9-11).

Yoshida does note explicitly teach the claimed controlled release dosage form.

Ogorka teaches a controlled release dosage form comprising therapeutically effective dose of active agent such as psychopharmacological agents, antidepressants, and anti-Alzheimer (abstract; and paragraphs 0028-0033). The composition further comprises hydrophilic gel forming substance such as methylcellulose, hydroxypropylmethyl cellulose, and sodium carboxymethyl cellulose (paragraph 0044). The composition is suitable for once a day oral administration (paragraph 0037). Thus, it would have been obvious to one of ordinary kill in the art at the time the invention was made to modify the composition of Yoshida using the controlled release dosage form in view of the teaching of Ogorka, because Ogorka teaches a dosage form that is

convenience for patient (0037), because Ogorka teaches a dosage form that provides desired controlled release of active agent suitable for the treatment of Alzheimer, and because Yoshida teaches an oral dosage form comprising active agent suitable for the treatment of Alzheimer.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. US 4,690,949, in view of Sauer et al. US 2001/0003588 A1.

Yoshida is relied upon for the reason stated above. Yoshida does note explicitly teach the controlled release dosage form suitable for twice or three-time daily.

Sauer teaches a controlled release formulation comprising immediate release beads and controlled release beads (coated beads) suitable for oral administration of drugs (paragraphs 0027 and 0029). The formulation is suitable for twice a day administration (claim 2). Thus, it would have been obvious to one of ordinary kill in the art at the time the invention was made to modify the composition of Yoshida using the controlled release dosage form in view of the teaching of Sauer to obtain the claimed invention, because Sauer teaches a dosage form that provides desired controlled release of active agent suitable for the treatment of Alzheimer (abstract; and claims), and because Yoshida teaches an oral dosage form comprising active agent suitable for the treatment of Alzheimer.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. US 4,690,949, in view of Vandecruys et al. 6,667,060.

Yoshida is relied upon for the reason stated above. Yoshida does note explicitly teach the controlled release dosage form comprising an immediate release form.

Vandecruys teaches a controlled release composition suitable for once daily oral administration comprising 0.01-50% active agent, and 25-60% cellulose polymer (abstract; and column 15, lines 25-61). The composition further comprises an immediate release dosage form (column 17, lines 46-50). Thus, it would have been obvious to one of ordinary kill in the art at the time the invention was made to modify the composition of Yoshida using the controlled release dosage form in view of the teaching of Vandecruys, because Vandecruys teaches a controlled release dosage form suitable for a variety of active agents, including antidepressant and antipsychotic agents, because Vandecruys teaches a controlled release dosage form that improved patient's compliance (column 2, lines 10-22), and because Yoshida teaches a dosage form comprising active agent and pharmaceutically acceptable excipient suitable for oral administration of drug useful for the treatment of dementia.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yokokawa et al. is cited for the teaching of composition comprising L-threo-DOPS.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm; Thurs. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615